

CLAIMS

1. (Original) A hydroxyethylstarch having an average molecular weight, M_w , of greater than or equal to 500,000, characterized by having a molar substitution MS of from 0.25 to 0.5 and a C_2/C_6 ratio of from 2 to below 8.

Claims 2-23 (Canceled)

24. (New) The hydroxyethylstarch according to claim 1, wherein the molar substitution MS is from 0.35 to 0.5, preferably from 0.39 to smaller than or equal to 0.45, especially from greater than 0.4 to 0.44.

25. (New) The hydroxyethylstarch according to claim 1, wherein the average molecular weight is from above 600,000 to 1,500,000, preferably from 620,000 to 1,200,000, more preferably from 700,000 to 1,000,000.

26. (New) The hydroxyethylstarch according to claim 1, wherein the said C_2/C_6 ratio is from 2 to 7, preferably from 2.5 to smaller than or equal to 7, more preferably from 2.5 to 6, even more preferably from 4 to 6.

27. (New) The hydroxyethylstarch according to claim 1, wherein the hydroxyethylstarch is obtainable from a waxy maize starch.

28. (New) The hydroxyethylstarch according to claim 24, wherein the average molecular weight is from above 600,000 to 1,500,000, preferably from 620,000 to 1,200,000, more preferably from 700,000 to 1,000,000.

29. (New) The hydroxyethylstarch according to claim 24, wherein the C_2/C_6 ratio is from 2 to 7, preferably from 2.5 to smaller than or equal to 7, more preferably from 2.5 to 6, even more preferably from 4 to 6.

30. (New) The hydroxyethylstarch according to claim 25, wherein the C_2/C_6 ratio is from 2 to 7, preferably from 2.5 to smaller than or equal to 7, more preferably from 2.5 to 6, even more preferably from 4 to 6.

31. (New) The hydroxyethylstarch according to claim 24, wherein the hydroxyethylstarch is obtainable from a waxy maize starch.

32. (New) The hydroxyethylstarch according to claim 25, wherein the hydroxyethylstarch is obtainable from a waxy maize starch.

33. (New) The hydroxyethylstarch according to claim 26, wherein the hydroxyethylstarch is obtainable from a waxy maize starch.

34. (New) A pharmaceutical formulation comprising a hydroxyethylstarch comprising an average molecular weight, M_w , of greater than or equal to 500,000, a molar substitution MS of from 0.25 to 0.5 and a C_2/C_6 ratio of from 2 to below 8.

35. (New) The pharmaceutical formulation according to claim 34, wherein the pharmaceutical formulation is in the form of at least one of an aqueous solution and a colloidal aqueous solution.

36. (New) The pharmaceutical formulation according to claim 34, wherein the hydroxyethylstarch in the formulation is in a concentration of up to 20%, preferably from 0.5 to 15%, more preferably from 2 to 12%.

37. (New) The pharmaceutical formulation according to claim 34, wherein the pharmaceutical formulation further comprises sodium chloride, preferably in a concentration of 0.9%.

38. (New) The pharmaceutical formulation according to claim 34, wherein the pharmaceutical formulation further comprises plasma-adapted electrolytes.

39. (New) The pharmaceutical formulation according to claim 34, wherein the pharmaceutical formulation is in the form of at least one of a buffered solution and a solution with metabolizable anions.

40. (New) The pharmaceutical formulation according to claim 34, wherein the pharmaceutical formulation is in the form of a hypertonic solution.

41. (New) The pharmaceutical formulation according to claim 34, wherein the hydroxyethylstarch is at least one of sterile filtered and heat sterilized.

42. (New) The pharmaceutical formulation according to claim 34, characterized by being a volume replacement.

43. (New) The pharmaceutical formulation according to claim 34, further comprising at least one pharmaceutically active ingredient.

44. (New) The pharmaceutical formulation according to claim 35, wherein the hydroxyethylstarch is in a concentration of up to 20%, preferably from 0.5 to 15%, more preferably from 2 to 12%.

45. (New) The pharmaceutical formulation according to claim 35, further comprising sodium chloride.

46. (New) The pharmaceutical formulation according to claim 35, further comprising plasma-adapted electrolytes.

47. (New) The pharmaceutical formulation according to claim 35, wherein the pharmaceutical formulation is in the form of at least one of a buffered solution and a solution with metabolizable anions.

48. (New) The pharmaceutical formulation according to claim 35, wherein the pharmaceutical solution is in the form of a hypertonic solution.

49. (New) The pharmaceutical formulation according to claim 35, wherein the hydroxyethylstarch is at least one of sterile filtered and heat sterilized.

50. (New) The pharmaceutical formulation according to claim 35, characterized by being a volume replacement.

51. (New) The pharmaceutical formulation according to claim 35, further comprising at least one pharmaceutically active ingredient.

52. (New) A method of preparing a plasma replacement or plasma expander, said method comprising the step of preparing a pharmaceutical formulation comprising a hydroxyethylstarch comprising an average molecular weight, Mw, of greater than or equal to 500,000, characterized by having a molar substitution MS of from 0.25 to 0.5 and a C₂/C₆ ratio of from 2 to below 8.

53. (New) The method of claim 52, wherein the pharmaceutical formulation is in the form of at least one of an aqueous solution and a colloidal aqueous solution.

54. (New) The method of claim 52, wherein the hydroxyethylstarch is in a concentration of up to 20%, preferably from 0.5 to 15%, more preferably from 2 to 12%.

55. (New) The method of claim 52, further comprising sodium chloride, preferably in a concentration of 0.9% in the pharmaceutical formulation.

56. (New) The method of claim 52, further comprising plasma-adapted electrolytes.

57. (New) The method of claim 52, wherein the pharmaceutical formulation is in the form of at least one of a buffered solution and a solution with metabolizable anions.

58. (New) The method of claim 52, wherein the pharmaceutical formulation is in a form of a hypertonic solution.

59. (New) The method of claim 52, wherein the hydroxyethylstarch is at least one of sterile filtered and heat sterilized.

60. (New) The method of claim 52, wherein the pharmaceutical formulation is used as a volume replacement.

61. (New) The method of claim 52, wherein further comprising at least one pharmaceutically active ingredient.

62. (New) A process for preparing a hydroxyethylstarch comprising the steps:

(i) reacting water-suspended starch with ethylene oxide; and

(ii) partially hydrolyzing a starch derivative with acid until a desired range of average molecular weight of the hydroxyethylstarch is reached; and

wherein the hydroxyethylstarch comprises an average molecular weight, Mw, of greater than or equal to 500,000, characterized by having a molar substitution MS of from 0.25 to 0.5 and a C₂/C₆ ratio of from 2 to below 8.

63. (New) The process according to claim 62, wherein an alkalizing agent is added to said water-suspended starch.

64. (New) The process according to claim 62, wherein an alkalizing agent is added to said suspended starch in such an amount that a molar ratio of alkalizing agent to starch is larger than 0.2, preferably from 0.25 to 1, especially from 0.3 to 0.8.

65. (New) The process according to claim 62, further comprising the steps of sterilization.

66. (New) The process according to claim 62, wherein the suspended starch is corn starch.

67. (New) The process according to claim 62, wherein the acid is hydrochloric acid.

68. (New) The process according to claim 63, wherein the alkalizing agent is NaOH.

69. (New) The process according to claim 65, further comprising the step of ultrafiltration.

70. (New) Use of a pharmaceutical formulation for at least one of maintaining normovolemia, improving macro- and microcirculation, improving nutritive oxygen supply, stabilizing hemodynamics, improving volume efficiency, reducing plasma viscosity, increasing anemia tolerance, and for hemodilution, wherein the pharmaceutical formulation contains a hydroxyethylstarch having an average molecular weight, Mw, of greater than or equal to 500,000, characterized by having a molar substitution MS of from 0.25 to 0.5 and a C₂/C₆ ratio of from 2 to below 8, and introducing the pharmaceutical formulation in a treatment process.

71. (New) The use of a pharmaceutical formulation according to claim 70, wherein the hemodilution involves therapeutic hemodilution in disturbed blood supply and arterial diseases.

72. (New) The use of a pharmaceutical formulation according to claim 71, wherein the arterial diseases involves peripheral arterial occlusive diseases.

73. (New) The use of a pharmaceutical formulation according to claim 70, wherein the pharmaceutical formulation is in the form of at least one of an aqueous solution and a colloidal aqueous solution.

74. (New) The use of a pharmaceutical formulation according to claim 70, wherein the hydroxyethylstarch is in a concentration of up to 20%, preferably from 0.5 to 15%, more preferably from 2 to 12%.

75. (New) The use of a pharmaceutical formulation according to claim 70, wherein the pharmaceutical formulation further contains a sodium chloride, preferably in a concentration of 0.9%.

76. (New) The use of a pharmaceutical formulation according to claim 70, wherein the pharmaceutical formulation further includes plasma-adapted electrolytes.

77. (New) The use of a pharmaceutical formulation according to claim 70, wherein the pharmaceutical formulation is in the form of at least one of a buffered solution and a solution with metabolizable anions.

78. (New) The use of a pharmaceutical formulation according to claim 70, wherein the pharmaceutical formulation is in the form of a hypertonic solution.

79. (New) A kit comprising separately:

- (i) a hydroxyethylstarch; and
- (ii) a sterile salt solution

wherein the hydroxyethylstarch comprises an average molecular weight, M_w , of greater

than or equal to 500,000, characterized by having a molar substitution MS of from 0.25 to 0.5 and a C_2/C_6 ratio of from 2 to below 8.

80. (New) The kit of claim 79, wherein the sterile salt solution is sodium chloride solution.

81. (New) The kit of claim 79, further comprising at least one pharmaceutically active ingredient.

82. (New) The kit of claim 79, wherein the molar substitution MS is from 0.35 to 0.5, preferably from 0.39 to smaller than or equal to 0.45, especially from greater than 0.4 to 0.44.

83. (New) The kit of claim 79, wherein the average molecular weight is from above 600,000 to 1,500,000, preferably from 620,000 to 1,200,000, more preferably from 700,000 to 1,000,000.

84. (New) The kit of claim 79, wherein the C_2/C_6 ratio is from 2 to 7, preferably from 2.5 to smaller than or equal to 7, more preferably from 2.5 to 6, even more preferably from 4 to 6.

85. (New) The kit of claim 79, wherein the average molecular weight is from above 600,000 to 1,500,000, preferably from 620,000 to 1,200,000, more preferably from 700,000 to 1,000,000.

86. (New) The kit of claim 79, wherein the hydroxyethylstarch and the sterile salt solution are in separated compartments in a multi-compartment bag.

87. (New) The kit of claim 81, wherein the hydroxyethylstarch, the sterile salt solution, and the at least one pharmaceutically active ingredient are in separated compartments in a multi-compartment bag.